

Notice of Allowability

| Application No. | Applicant(s) |
|----------------------|--------------|
| 10/019,613 | MARIN ET AL. |
| Examiner | Art Unit |
| Raymond J Henley III | 1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to Applicants' Amendment filed September 20, 2004.
2. The allowed claim(s) is/are 13-17 and 19-26.
3. The drawings filed on _____ are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

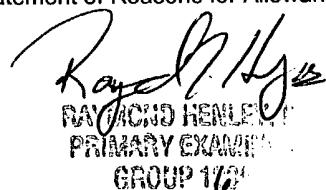
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
Paper No./Mail Date 10/05/2004.
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.



RAYMOND J. HENLEY III
PRIMARY EXAMINER
GROUP 16

EXAMINER'S AMENDMENT

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on October 5, 2004, Rochelle K. Seide requested an extension of time for ONE (1) MONTH and authorized the Director to charge Deposit Account No. 02-4377 the required fee of \$320.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Applicants' amendment filed September 20, 2004 places the application in condition for allowance, but is non-compliant because all claims have not been listed. Beginning on the next page, the Examiner's amendment appears which perfects Applicants' amendment by inserting --- Claims 1-12 (canceled)--- below "Listing of Claims".

AMENDMENTS TO THE CLAIMS

The listing of claims provided below will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claims 1-12 (canceled)

13. (Previously presented) A method for the treatment of heart failure in a mammal which comprises administering a cortisol antagonist to said mammal in an amount effective to treat the heart failure, with the proviso that said cortisol antagonist is not clonidine.
14. (Previously presented) The method of claim 13 wherein the heart failure is selected from the group consisting of congestive heart failure, diastolic heart failure, low-output heart failure, right-sided heart failure, cardiac hypertrophy, and cardiac fibrosis.
15. (Previously presented) The method of claim 14 wherein the cortisol antagonist is an inhibitor of cortisol synthesis.
16. (Previously presented) The method of claim 15 wherein the inhibitor of cortisol synthesis is ketoconazole or a derivative thereof.
17. (Previously presented) The method of claim 16 wherein the cortisol synthesis inhibitor is a Cis-2S,4R and/or Cis-2R, 4S isomer of ketoconazole.
18. (Cancelled)
19. (Previously presented) A method for the treatment of one or more symptoms associated with heart failure selected from the group comprising edema of lower limbs, pulmonary edema, dyspnea, liver enlargement, increased heart rate, reduced stroke volume, shortness of breath and exercise intolerance which comprises administering, in a daily dose, a cortisol antagonist to a mammalian subject, with the proviso that said

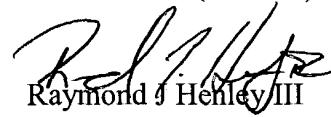
cortisol antagonist is not clonidine.

20. (Previously presented) The method of claim 19 wherein the symptom is pulmonary edema.
21. (Previously presented) The method of claim 19 wherein the daily dose of the cortisol antagonist administered to the subject being treated is 100-1,200 mg.
22. (Currently amended) The method of claim 19 wherein the daily dose of the cortisol antagonist administered to the subject being treated is 200-800 100-800 mg.
23. (Currently amended) The method of claim 19 wherein the cortisol antagonist is ketoconazole and the daily dose of cortisol antagonist ketoconazole being administered to the subject being treated is 300-600 mg.
24. (Previously presented) The method of claim 13, wherein the daily dose of cortisol antagonist being administered to the subject being treated is 100-1200 mg.
25. (Currently amended) The method of claim 13, wherein the daily dose of cortisol antagonist being administered to the subject being treated is 200-800 100-800 mg.
26. (Currently amended) The method of claim 13, wherein the cortisol antagonist is ketoconazole and the daily dose of cortisol antagonist ketoconazole being administered to the subject being treated is 300-600 mg.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J. Henley III
Primary Examiner
Art Unit 1614

October 5, 2004